

Remarks

Claims 1 and 3-10 were pending in the subject application. By this Amendment, claims 1 and 5 have been amended, and claims 3, 4, 6, 7, 9 and 10 have been cancelled. Support for the amendments to the claims can be found throughout the specification and claims as originally filed, including, for example, at page 5, lines 11-20, and page 8, lines 1-10. No new matter has been added by these amendments. Accordingly, claims 1, 5, and 8 are before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicant wishes to thank Examiner Snow for the courtesy extended to the undersigned and Mr. Frank during the personal Examiner Interview conducted January 14, 2009. This response and the amendments set forth herein are submitted in accordance with the substance of that interview and constitute a summary of the substance of that interview.

Initially, the Office Action has objected to the subject Specification under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. By this Amendment, the applicant has amended the subject specification to delete the "Brief Description of the Drawings," thereby rendering this objection moot.

The drawings have been objected to under 37 CFR 1.83(a). By this amendment, the applicants have also deleted Figures 1 and 2 that were added to the specification by Amendment on October 15, 2007.

Claims 1, 3, 6, and 7 have been rejected under 35 U.S.C. §102(c) as being anticipated by Irie (U.S. Patent No. 5,895,411). The applicant respectfully traverses this ground for rejection because the cited reference does not disclose each and every element of the applicant's claimed method for soft tissue augmentation.

The subject invention is readily distinguishable from the invention described in the '411 patent. Specifically, the particles used according to the '411 patent are delivered inside a blood

vessel. Thus, this procedure is very different from the currently-claimed invention wherein blood vessels grow through a hollow cylinder thereby securing the pellets in a specific desired location. Certainly, in the practice of the current invention, one would not want the pellets to be inside a blood vessel. Thus, the current invention is the antithesis of what is described in the '411 patent. The claims have been amended herein to clarify this aspect of the current invention by setting forth, for example, the dimensions of the cylinder and by reciting specific applications of the method of the subject invention.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

As noted above, the '411 patent does not disclose a method whereby capillary ingrowth into a hollow-conduit cylinder made from specific materials results in the cylinder being advantageously anchored at the desired location for treatment of specific conditions. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) based on the Irie '411 patent.

Claims 1, and 3-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ersek *et al.* (U.S. Patent No. 5,336,263). The applicant respectfully traverses this ground for rejection because the cited reference does not disclose or suggest the applicant's unique and advantageous method.

Although Ersek *et al.* and the current invention address a similar problem — migration of particles from a desired location — they do so in different ways. Ersak *et al.* provide “textured micro particles” (column 4, lines 58-61; claim 1). Ersek *et al.* further state that the textured microparticles present generally amorphous surfaces with indentations having irregular configurations and surfaces. This is in contrast to the pellets of the current invention, which have a defined shape (cylindrical) and have a conduit running through the pellet.

Although Figure 2 of the Ersek *et al.* reference appears to show a particle that has a hole that runs completely through the particle, this particle is still very different (structurally and functionally) from the smooth hollow cylinders claimed by the current applicant. Specifically, unlike the applicants smooth hollow cylinders of defined dimensions, the Ersek *et al.* particles are “textured,” generally “amorphous,” and have large surface irregularities.

The differences in structure between the Ersek *et al.* particles and the pellets used according to the current invention result in important functional advantages in the context of the method claimed by the current applicant. For example, whereas the Ersek *et al.* try to promote “encapsulation” of the particle (column 3, lines 15-17) the current invention provides a method for anchoring the pellets in place through growth of capillaries and such through the internal hollow conduit of the pellet. This is set forth in the applicant’s claims and clearly described in the applicant’s specification. See, for example, page 3, lines 5-8; page 4, lines 13-16; and page 5, lines 28-29.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant’s invention does not make the modification or application obvious unless “there was an apparent reason to combine the known elements in the fashion claimed” by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicants’ disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Sponnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

As noted above, Ersek *et al.* uses a different strategy, *i.e.* encapsulation, to address the migration problem whereas the current invention, through the use of entirely different shaped pellets, addresses the problem by promoting anchoring of hollow cylinders via ingrowth through a hollow conduit. Ersek *et al.* provide no suggestion of the method claimed by the current applicant.

Therefore, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on the Ersek *et al.* reference.

Claim 8 has been rejected under 35 U.S.C. §103(a) as being unpatentable over applicant's specification in view of Ersek *et al.* (U.S. Patent No. 5,336,263). The applicant respectfully traverses this ground for rejection because the cited references, either taken alone or in combination, do not disclose or suggest the applicant's unique and advantageous method.

The applicant's mere statement of the problem to be solved does not, even in combination with Ersek *et al.*, disclose or suggest the particular method now claimed. This is especially true since, as discussed above, Ersek *et al.* propose an entirely different solution to the problem.

Therefore, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on the applicant's specification in view of the Ersek *et al.* reference.

In view of the foregoing remarks and the amendment above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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